THIS OPINION WAS NOT WRITTEN FOR PUBLICATION

The opinion in support of the decision being entered today (1) was not written for publication in a law journal and (2) is not binding precedent of the Board.

Paper No. 19

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

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Ex parte YING MA and YOICHIRO ITO

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Appeal No. 1997-3811
Application No. 08/357,845

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ON BRIEF

_____

Before GARRIS, OWENS, and KRATZ, Administrative Patent Judges.
KRATZ, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on appeal from the examiner's final rejection of claims 1-7. Claims 8-20, which are all of the other claims pending in this application, have been withdrawn from consideration by the examiner as drawn to non-elected inventions.

BACKGROUND

Appellants' invention relates to a method of separating enantiomers of a racemic compound mixture from each other using high-speed countercurrent chromatography involving several particularly specified steps. An understanding of the invention can be derived from a reading of exemplary claim 1, which is reproduced below.

> 1. A method for separating a quantity of the (+) and (-) enantiomers of a racemic compound mixture from each other using high-speed countercurrent chromatography, comprising:
>
> (a) adding a chiral selector to a first liquid phase of two pre-equilibrated immiscible liquid phases and charging a countercurrent chromatographic centrifuge column with said first liquid phase, thereby producing a countercurrent chromatographic centrifuge column charged with said chiral selector and said first liquid phase;
>
> (b) introducing said racemic compound mixture into said countercurrent chromatographic centrifuge column thus charged with said chiral selector and said first liquid phase; and
>
> (c) passing a second liquid phase through said countercurrent chromatographic centrifuge column thus charged with said mixture, said chiral selector

and said first liquid phase, to elute said (+) enantiomer and said (-) enantiomer from said countercurrent chromatographic centrifuge column,

wherein said quantity is from 1 mg to 1 kg.

In addition to alleged admitted prior art[1], the prior art references of record relied upon by the examiner in rejecting the appealed claims are:

Pirkle et al. (Pirkle '293) 5,256,293 Oct. 26, 1993

Pirkle et al. (Pirkle '440) 5,290,440 Mar. 01, 1994

Cahnmann et al., "Synthesis and characterization of N-bromoacetyl-3,3',5-triiodo-L-thyronine," Journal of Chromatography Vol. 538 (1991), pages 165-175 (Cahnmann).

Pirkle, "Chiral stationary phase design Use of intercalative effects to enhance enantioselectivity," Journal of Chromatography Vol. 641 (1993), pages 11-19 (Pirkle article).

Claims 1-7 stand rejected under 35 U.S.C. § 102 as being anticipated by or, in the alternative, under 35 U.S.C. § 103 as being unpatentable over Pirkle '440. Claims 1-7 stand

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[1] See specification at pages 1-5, page 8, lines 22-28 and page 17, last paragraph.

rejected under 35 U.S.C. § 102 as being anticipated by or, in the alternative, under 35 U.S.C. § 103 as being unpatentable over Pirkle ‘293. Claims 1-7 stand rejected under 35 U.S.C. § 103 as being unpatentable over Pirkle ‘440 or Pirkle ‘293, each in view of admitted prior art set forth at pages 1-5 and the penultimate
full paragraph of page 8 of appellants’ specification and Cahnmann. Claim 5 stands rejected under 35 U.S.C. § 103 as being unpatentable over Pirkle ‘440 or Pirkle ‘293, each in view of admitted prior art set forth at pages 1-5 and the penultimate full paragraph of page 8 of appellants’ specification, Cahnmann, that which is admitted to be old in the last paragraph of page 17 of the specification and the Pirkle article.

OPINION

Upon careful review of the entire record including the respective positions advanced by appellants and the examiner, we find ourselves in agreement with appellants that the examiner has failed to carry the burden of establishing a *prima facie* case of obviousness or anticipation. Accordingly, we will not sustain any of the examiner's rejections.

Rejections under 35 U.S.C. § 102

The examiner has the initial burden of establishing a *prima facie* case of anticipation by pointing out where all of the claim limitations are described in a single reference. *See In re Spada*, 911 F.2d 705, 708, 15 USPQ2d 1655, 1657 (Fed. Cir. 1990); *In re King*, 801 F.2d 1324, 1327, 231 USPQ 136, 138-39 (Fed. Cir. 1986). This the examiner has not done.

All of the claims on appeal require a method of separating a specified quantity of the (+) and (-) enantiomers of a racemic compound mixture from each other using high-speed countercurrent chromatography. The method of claim 1, the sole independent claim on appeal, includes the following steps:

> (a) adding a chiral selector to a first liquid phase of two pre-equilibrated immiscible liquid phases and charging a countercurrent chromatographic centrifuge column with said first liquid phase;

> (b) introducing said racemic compound mixture into said countercurrent chromatographic centrifuge column thus charged with said chiral selector and said first liquid phase; and
>
> (c) passing a second liquid phase through said countercurrent chromatographic centrifuge column thus charged with said mixture, said chiral selector and said first liquid phase, to elute said (+) enantiomer and said (-) enantiomer from said countercurrent chromatographic centrifuge column,

wherein said quantity is from 1 mg to 1kg.

Both Pirkle ‘440 and Pirkle ‘293 disclose a process for separating enantiomers utilizing a chiral selector. Each of Pirkle ‘440 and Pirkle ‘293 describe methods for separating enantiomers using high performance liquid chromatographic columns and enantioselective membrane transport devices with some particularity. See, e.g., column 9, line 55 through column 12, line 9 of Pirkle ‘440 and column 17, line 61 through column 19, line 38 of Pirkle ‘293. Moreover, each of Pirkle ‘440 and Pirkle ‘293 generally describe countercurrent chromatographic devices as an alternative to the above-noted separation devices as repeatedly noted by the examiner in the answer.

See column 4, lines 45-52 of Pirkle ‘440 and column 7, lines 8-13 of Pirkle ‘293.

The examiner has not pointed out where in either applied reference there is an explicit and particular description of how any such countercurrent chromatographic device was to be employed in any specific process for separating enantiomers, let alone how such a device was to be used in a method corresponding to appellants’ separation method. Rather, the examiner takes the position that an ordinarily skilled artisan “would employ the standard steps that define countercurrent chromatography” (answer, pages 3 and 4) in either Pirkle ‘440 or Pirkle ‘293. In so doing, the examiner essentially urges that the use of such a

countercurrent device in the enantiomeric separation processes of either Pirkle patent would have necessarily resulted in the method of representative appealed claim 1. According to the examiner (answer, pages 3 and 4), this is so since appealed “claim 1 merely recites the standard steps that a person of

ordinary skill would use when instructed to use a chiral selector in a countercurrent chromatographic device."

We disagree. Anticipation under 35 U.S.C. § 102 requires a prior art reference to disclose, either expressly or under the principles of inherency, each and every element set forth in the rejected claims. See *RCA Corp. v. Applied Digital Data Systems, Inc.*, 730 F.2d 1440, 1044, 221 USPQ 385, 388 (Fed. Cir.), *cert. dismissed sub nom., Hazeltine Corp.v. RCA Corp.*, 468 US 1228 (1984). Here, the examiner has not shown where each of Pirkle '440 and Pirkle '293 have expressly described each and every limitation of appealed claim 1. Nor has the examiner reasonably established, under the principles of inherency, that each of Pirkle '440 and Pirkle '293 necessarily describe a process including each and every limitation of appellants' process by merely asserting that the herein claimed process steps are of a standard nature.

Anticipation is a factual determination. *See In re Baxter Travenol Labs.*, 952 F.2d 388, 390, 21 USPQ2d 1281, 1283 (Fed. Cir. 1991) (citing *In re Bond*, 910 F.2d 831, 833, 15 USPQ2d 1566, 1567 (Fed. Cir. 1990). In our view, the examiner has

not established with reasonable certitude that the reference to countercurrent chromatographic devices in each of the applied Pirkle patents coupled with the particular description of enantiomer separation processes using other specified separation equipment in those patents necessarily constitutes a description of appellants' process including the combination of steps recited in appealed claim 1. In particular, the examiner has not shown that either applied Pirkle patent necessarily describes a separation method that includes the addition of a chiral selector to a first liquid phase that is charged to a countercurrent centrifuge column, the introduction of a racemic mixture into the column and the passage of a second liquid phase through the so charged column to elute enantiomers therefrom. Hence, the examiner has simply not carried the initial burden of establishing a *prima facie* case of anticipation as to the appealed claims. Consequently, we reverse the rejections under 35 U.S.C. § 102.

Rejections under 35 U.S.C. § 103

In an attempt to establish that appellants' process, as defined in representative claim 1, solely involves standard steps that an ordinarily skilled artisan would have obviously employed in using any countercurrent chromatographic device in either Pirkle patent, the examiner (1) suggests that "optimization" would have led one of ordinary skill in the art to the claimed process; and (2) relies on alleged admitted prior art in appellants' specification and Cahnmann to establish the obviousness of the herein claimed process.

Of course, it is axiomatic that consideration of the prior art cited by the examiner must, of necessity, include consideration of the admitted state of the art found in appellants' specification. *In re Hedges*, 783 F.2d 1038, 228 USPQ 685 (Fed. Cir. 1986); *In re Davis*, 305 F.2d 501, 503, 134 USPQ 256, 258 (CCPA 1962). Additionally, it is well settled that the relevance of a prior art reference to the obviousness conclusion is not confined to preferred or illustrative embodiments. Rather, a prior art reference may be relied upon for all that it

would have reasonably conveyed to one having ordinary skill in the art. *In re Young*, 927 F.2d 588, 591, 18 USPQ2d 1089, 1091 (Fed. Cir. 1991); *Merck & Co., Inc. v. Biocraft Laboratories, Inc.*, 874 F.2d 804, 807, 10 USPQ2d 1843,1846 (Fed. Cir. 1989).

The difficulty we have with the examiner's position stems from the fact that the examiner has not offered a reasonable explanation as to how the combined teachings of either Pirkle '440 or Pirkle '293 taken together with the admitted prior art and with or without Cahnmann would have reasonably suggested carrying out the separation process by adding a chiral separator to the first liquid phase (stationary phase)[2] and passing a second liquid phase through a countercurrent chromatographic centrifuge to elute the enantiomers therefrom. Concerning this matter, we note that the examiner refers to portions of the applied Pirkle patents that make mention of using a chiral selector in a mobile phase (answer, page 11, lines 2-16).

We agree with the examiner that both applied Pirkle patents particularly refer to the use of a chiral selector in

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[2] See specification at page 1, lines 9-12 and page 5, lines 7-11, for example.

a mobile phase when employing semi-permeable membranes for separation. See column 11, line 16 through column 12, line 9 of Pirkle ‘440 and column 19, lines 16-42 of Pirkle ‘293. However, the examiner has not established, on this record, why the teachings of the Pirkle patents with respect to using a chiral selector as part of a mobile phase in the semi-permeable membrane embodiment described therein would have led one of ordinary skill in the art to add a chiral selector to the first liquid phase (stationary phase) charged to a countercurrent centrifuge column as herein claimed. Additionally, the examiner has not shown how any particular “optimization” of countercurrent chromatgraphy separation and/or the applied Cahnmann reference makes up for the above-noted deficiency. Nor has the examiner demonstrated how the published article by Pirkle and additional alleged admitted prior art as further applied in a separate rejection against claim 5 cure the above-noted deficiency of the combined prior art teachings.

The examiner has simply not made the case as to why one of ordinary skill in the art would have been led to choose the herein claimed particular process steps from the combined

references' teachings. Significantly, appellants' contentions regarding the many other alternative options that were available for consideration by one of ordinary skill in the art who may have attempted to separate enantiomers based on the bare discloure of countercurrent chromatographic devices in the applied Pirkle patents have not been fully addresssed by the examiner in the answer. See the carryover paragraph, pages 4 and 5 and pages 7-11 of the brief.

For the foregoing reasons, we find that the examiner has not established a *prima facie* case of obviousness with respect to any of the examiner's § 103 rejections.

CONCLUSION

The decision of the examiner to reject claims 1-7 under 35 U.S.C. § 102 as being anticipated by or, in the alternative, under 35 U.S.C. § 103 as being unpatentable over Pirkle '440; to reject claims 1-7 under 35 U.S.C. § 102 as being anticipated by or, in the alternative, under 35 U.S.C. § 103 as being unpatentable over Pirkle '293; to reject claims 1-7 under 35 U.S.C. § 103 as being unpatentable over Pirkle '440 or Pirkle '293, each in view of admitted prior art set forth at pages 1-5 and the penultimate full paragraph of page

8 of appellants' specification and Cahnmann; and to reject claim 5 under 35 U.S.C. § 103 as being unpatentable over Pirkle '440 or Pirkle '293, each in view of admitted prior art set forth at pages 1-5 and the penultimate full paragraph of page 8 of appellants' specification, Cahnmann, that which is admitted to be old in the last paragraph of page 17 of the specification and the Pirkle article is reversed.

REVERSED

BRADLEY R. GARRIS Administrative Patent Judge	)
TERRY J. OWENS Administrative Patent Judge	) BOARD OF PATENT APPEALS AND INTERFERENCES
PETER F. KRATZ	)

Administrative Patent Judge)

pfk/vsh

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